Decision Memo for Ventricular Assist Devices as Destination Therapy (CAG-00119R)

Decision Summary

The Centers for Medicare and Medicaid Services (CMS) modifies the facility criteria for Ventricular Assist Device (VAD) implantation as destination therapy as follows:

- Reducing the VAD implant volume standard from 15 VADs to 10 VADs or artificial hearts implanted over a three year period either as bridge-to-transplant or as destination therapy;
- The facility's VAD team must include a surgeon with the requisite volume;
- Changing the volume measurement period from January 1, 2001 through September 30, 2003 to a continuous 3-year period;
- Eliminating the requirement that the hospital must be a Medicare-approved heart transplant facility;
- Eliminating the opportunity for an exception to these standards;
- Naming the Interagency Registry for Mechanically Assisted Circulatory Support (INTERMACS) as the registry that satisfies the CMS reporting requirement;
- Requiring that facilities be approved under the "Disease-Specific Care Certification Program for Ventricular Assist Device" developed by the Joint Commission on Accreditation of Healthcare Organizations, dated February 2007, and establishing a time limit for existing facilities to complete this process; and
- Requiring current facilities to document their continued compliance with the current and modified requirements outlined in this NCD.

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Decision Memo

TO: Administrative File: CAG 00119R
Ventricular Assist Devices as Destination Therapy

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SUBJECT: Coverage Decision Memorandum for Ventricular Assist Devices as Destination Therapy

DATE: March 27, 2007

I. Decision

The Centers for Medicare and Medicaid Services (CMS) modifies the facility criteria for Ventricular Assist Device (VAD) implantation as destination therapy as follows:

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- Requiring that facilities be approved under the “Disease-Specific Care Certification Program for Ventricular Assist Device” developed by the Joint Commission on Accreditation of Healthcare Organizations, dated February 2007, and establishing a time limit for existing facilities to complete this process; and
- Requiring current facilities to document their continued compliance with the current and modified requirements outlined in this NCD.

II. Background

Ventricular Assist Devices (VADs) are mechanical pumps that take over or support the function of a damaged heart (the right, left or both ventricles) and improve hemodynamics and end-organ blood flow. Different VAD designs, including electrically or pneumatically powered, either implanted or paracorporeal (external), currently have Food and Drug Administration (FDA) approval for the indications listed below. Most of these devices assist the left ventricle and, therefore, are commonly referred to as left ventricular assist devices (LVAD).

Heart failure affects an estimated 5 million Americans and in 2001 resulted in 53,000 deaths. Heart failure is predominant in the elderly population with 80% of all heart failure hospitalizations involving patients aged 65 or greater. (Circulation 2005; 112; 154-235)

Although patients with mild to moderate heart failure have been shown to benefit from drug therapy, the survival and quality of life for those with severe failure, whose symptoms fail to respond to optimum medical management, remains limited. Cardiac transplantation is the only treatment that provides substantial benefit for end-stage heart failure (ESHF), but the available donor supply limits its application. In 2005, there were 2,125 heart transplants performed in the United States. While eligibility criteria differ among transplant centers, most Medicare beneficiaries are excluded from receiving a heart transplant because of age or such comorbid conditions as diabetes with end organ damage, chronic renal failure or other chronic disease. Only 209 of the total heart transplants in 2005 were performed in patients age 65 or over (based on OPTN data as of November 17, 2006).

VADs are currently used and approved for Medicare coverage in three groups of patients. The first group consists of patients who may require temporary ventricular support while recovering from cardiogenic shock following open heart surgery. The second group consists of patients who are not expected to recover adequate cardiac function, who have been approved for cardiac transplantation, and who require mechanical support to assist heart function until a donor heart becomes available. VADs used in this manner are often termed "bridge to transplant." The third group, often termed "destination therapy," consists of patients that require permanent circulatory support due to chronic ESHF. These patients require permanent support as they are generally not candidates for heart transplantation.

VAD implantation for destination therapy is currently approved only at facilities that meet specific facility standards outlined in CMS' 2003 NCD.

CMS received a formal request from the Joint Commission on the Accreditation of Healthcare Organizations (Joint Commission) to review the VAD destination therapy facility standards outlined in their Disease Specific Certification Program. On July 10, 2006, CMS began the NCD reconsideration process to open a formal review of the standards submitted by the Joint Commission and to determine whether or not facilities certified by the Joint Commission should be Medicare approved as VAD destination therapy facilities. In addition, CMS is reconsidering the facility criteria originally established in the October 1, 2003 NCD. The 2003 decision memorandum is available in it's entirety at http://www.cms.hhs.gov/mcd/viewdecisionmemo.asp?id=79. This July 10, 2006, reconsideration does not include a review of the clinical indications for Medicare coverage of VADs for destination therapy.

III. History of Medicare Coverage

The original (October 2003) policy regarding VADs used as DT is as follows:

Destination Therapy (effective for services performed on or after October 1, 2003)

Destination therapy is for patients that require permanent mechanical cardiac support. VADs used for destination therapy are covered only if they have received approval from the FDA for that purpose, and the device is used according to the FDA-approved labeling instructions. VADs are covered for patients who have chronic end-stage heart failure (New York Heart Association Class IV end-stage left ventricular failure for at least 90 days with a life expectancy of less than 2 years), are not candidates for heart transplantation, and meet all of the following conditions:

- The patient's Class IV heart failure symptoms have failed to respond to optimal medical management, including dietary salt restriction, diuretics, digitalis, beta-blockers, and ACE inhibitors (if tolerated) for at least 60 of the last 90 days;
- The patient has a left ventricular ejection fraction (LVEF) < 25%;
- The patient has demonstrated functional limitation with a peak oxygen consumption of < 12 ml/kg/min; or the patient has a continued need for intravenous inotropic therapy owing to symptomatic hypotension, decreasing renal function, or worsening pulmonary congestion; and,
- The patient has the appropriate body size (>1.5 m^2) to support the VAD implantation.

In addition, the Centers for Medicare & Medicaid Services (CMS) has determined that VAD implantation as destination therapy is reasonable and necessary only when the procedure is performed in a Medicare-approved heart transplant facility that, between January 1, 2001, and September 30, 2003, implanted at least 15 VADs as a bridge-to-transplant or as destination therapy. These devices must have been approved by the FDA for destination therapy or as a bridge-to-transplant, or have been implanted as part of an FDA investigational device exemption (IDE) trial for one of these two indications. The VADs implanted for other investigational indications or for support of blood circulation post-cardiotomy do not satisfy the volume requirement for this purpose. Since the relationship between volume and outcomes has not been well-established for VAD use, facilities that have minimal deficiencies in meeting this standard may apply and include a request for an exception based upon additional factors. Some of the factors CMS will consider are geographic location of the center, number of destination procedures performed, and patient outcomes from VAD procedures completed.

Also, this facility must be an active, continuous member of a national, audited registry that requires submission of health data on all VAD destination therapy patients from the date of implantation throughout the remainder of their lives. This registry must have the ability to accommodate data related to any device approved by the FDA for destination therapy regardless of manufacturer. The registry must also provide such routine reports as may be specified by CMS, and must have standards for data quality and timeliness of data submissions such that hospitals failing to meet them will be removed from membership. CMS believes that the registry sponsored by the International Society for Heart and Lung Transplantation is an example of a registry that meets these characteristics.

Hospitals also must have in place staff and procedures that ensure that prospective VAD recipients receive all information necessary to assist them in giving appropriate informed consent for the procedure so that they and their families are fully aware of the aftercare requirements and potential limitations, as well as benefits, following VAD implantation.

CMS plans to develop accreditation standards for facilities that implant VADs and, when implemented, VAD implantation will be considered reasonable and necessary only at accredited facilities.

A list of facilities eligible for Medicare reimbursement for VADs as destination therapy will be maintained on our website and available at www.cms.hhs.gov/coverage/lvadfacility.asp [change in website effective January 2006 to http://www.cms.hhs.gov/MedicareApprovedFacilitie/VAD/list.asp#TopOfPage]. In order to be placed on this list, facilities must submit a letter to the Director, Coverage and Analysis Group, 7500 Security Blvd, Mailstop C1-09-06, Baltimore, MD 21244. This letter must be received by CMS within 90 days of the issue date on this transmittal. The letter must include the following information:

- Facility's name and complete address;
- Facility's Medicare provider number;
- List of all implantations between Jan. 1, 2001, and Sept. 30, 2003, with the following information:

    - Date of implantation,
    - Indication for implantation (only destination and bridge-to-transplant can be reported; post-cardiotomy VAD implants are not to be included),
    - Device name and manufacturer, and,
    - Date of device removal and reason (e.g., transplantation, recovery, device malfunction), or date and cause of patient's death;
- Point-of-contact for questions with telephone number;
- Registry to which patient information will be submitted; and,
- Signature of a senior facility administrative official.

Facilities not meeting the minimal standards and requesting exception should, in addition to supplying the information above, include the factors that they deem critical in requesting the exception to the standards.

CMS will review the information contained in the above letters. When the review is complete, all necessary information is received, and criteria are met, CMS will include the name of the newly Medicare-approved facility on the CMS web site. No reimbursement for destination therapy will be made for implantations performed before the date the facility is added to the CMS web site. Each newly approved facility will also receive a formal letter from CMS stating the official approval date it was added to the list.

The complete October 2003 Medicare policy for VAD use, including post-cardiotomy and bridge to transplantation, is available in Appendix A of this document.

Medicare is a defined benefit program. An item or service must fall within a benefit category as a prerequisite to Medicare coverage. This issue was discussed as part of the October 2003 decision and at that time it was determined that VADs as destination therapy fall within the Inpatient Hospital Services benefit category (section 1861(b)(2) of the Social Security Act (the Act)), which describes supplies, appliances, and equipment furnished by the hospital, for use in the hospital, for the care and treatment of inpatients. After a VAD has been surgically implanted into the patient and when the patient is not a hospital patient, the replacement of an external part or parts may be covered under Medicare Part B within the Prosthetic Device benefit category (section 1861(s)(8) of the Act).

IV. Timeline of Recent Activities

July 10, 2006	CMS opens formal request from the Joint Commission to review standards of the Disease Specific Certification Program for VAD DT facilities in addition to beginning a review of the facility criteria established in the October 2003 decision. Initial 30-day public comment period begins.
August 9, 2006	Initial 30-day public comment period closes. Twelve comments are received.
December 27, 2006	Proposed decision memorandum is posted.
January 27, 2007	Comment period on the proposed decision closes with 11 comments.
February 2007	Updated Joint Commission standards received (see Appendix B).

V. FDA Status

On November 6, 2002, Thoratec, Inc. received FDA approval for an expanded Indication for Use for the Thoratec Heartmate SNAP VE LVAS for end-stage, non-transplantable patients. The approval states: “This device is now also indicated for use in patients with New York Heart Association Class IV end stage left ventricular failure who have received optimal medical therapy for at least 60 of the last 90 days, and who have a life expectancy of less than two years, and who are not eligible for cardiac transplantation. The device system is approved for use both inside and outside the hospital.”

VI. Assessment

Assessment Questions

In this assessment, CMS seeks to address the following questions:

- **Should CMS modify its facility criteria for ventricular assist devices as destination therapy?**
- **Are the Joint Commission standards at least equivalent to the CMS standards used to select facilities for ventricular assist devices as destination therapy?**

1. Evaluation of Current Medicare Facility Criteria

The Medicare decision to provide coverage for destination therapy included specific facility and personnel requirements. Due to the technically demanding nature of this procedure, the service was reasonable and necessary only when performed at facilities that met these requirements. CMS believed these were necessary to assure responsible translation and dissemination of what was then a new technology for high-risk patients, likely to live only a short time without the intervention.

Destination therapy was approved by Medicare only for patients with terminal heart failure who could not qualify for heart transplant, usually due to advanced age and/or comorbid conditions. It was not anticipated to be widely used and information available from the International Society of Heart and Lung Transplantation's Mechanical Circulatory Support Database shows this to be the case. Between January 1, 2002 and December 31, 2005, 180 destination procedures were reported to this database. We have detailed information on 158 of these patients showing that six months following device implantation 62% of patients were alive, including 6% who subsequently received a heart transplant after their physical conditions improved enough to make them transplant eligible, 38% had died and none recovered function of their native hearts.

The extremely small number of patients points to the necessity of assuring that destination therapy is limited to facilities having the experience and cardiac team (physicians and support personnel) most likely to assure a successful outcome for these very ill patients. The performance of the procedure needs to be limited to facilities and surgical teams with sufficient expertise in complex cardiac procedures. Our original decision required that destination therapy be performed at cardiac transplant facilities as an assurance that the required level of expertise would be available; however, in at least one instance in which a facility was approved as an exception to this requirement, its high volume of non-transplant complex cardiac surgery also provided the necessary experience that has resulted in success with destination therapy.

The small numbers of patients and complexity of the patient care, including the surgical procedure and the extended aftercare, led CMS to believe that ongoing collection of information about destination patients would be necessary to assure that, among other things, individual patients received care only at facilities continuing to meet high standards.

Registry participation
The International Society of Heart and Lung Transplantation was operating the Mechanical Circulatory Support Database (MCSD) in 2003 when the original destination therapy policy became effective. At the time, CMS identified this as the only available registry meeting the CMS reporting requirements for destination therapy VAD implantations. In 2005, the MCSD was superseded by the Interagency Registry for Mechanically Assisted Circulatory Support (INTERMACS). This registry is funded by the National Heart Lung and Blood Institute of the National Institutes of Health.

Transplant facility status
All but one of the facilities initially approved by CMS for destination therapy coverage was already approved as a heart transplant facility. It was our opinion that the experience gained with transplant patients most closely approximated that which would be necessary to maximize the chance of a successful outcome for a destination therapy patient. However, a non-transplant facility successfully sought an exception for initial coverage and continues to be very active in destination therapy and other VAD surgeries, with good outcomes. This facility was able to demonstrate that the appropriate infrastructure was in place in the absence of a transplant program.

Procedure volume
In the absence of prior experience with destination therapy, but understanding that it required commitment by a hospital in terms of providing experienced staff and adequate facilities to support the long-term care of seriously ill cardiac patients as well as the ability to perform highly complex cardiac surgery, CMS' facility approval criteria established 15 as the minimum number of procedures (destination therapy as part of the pivotal clinical trial or bridge-to-transplant) that must have been performed by a facility in the 33 month period between 01/01/01 and 09/30/03 to qualify for approval. Sixty-nine facilities were certified, including 13 that were granted an exception to stated criteria. As mentioned above, one facility was not a transplant facility, but had evidence of high volume and high quality, complex cardiac surgeries, which CMS believed sufficed as a substitute for transplantation experience. Twelve facilities did not meet the required volume of 15 VAD procedures; however, close review of their applications demonstrated their long-term commitment to their VAD programs' recently increased volumes and being on track to reach 15 implants in the very near future. CMS determined at that time that it was reasonable for destination VADs to be implanted in facilities nearing the requisite 15 implants, even though they had not quite achieved that number by the cut-off date in October 2003.

CMS recognizes that the two periods (01/01-09/03 [the time period for certification under our existing NCD] and 2002-2005 [the period for which data is currently available from the Mechanical Circulatory Support Device registry]) overlap and are not identical. CMS chose a 30 month period that encompassed a portion of the pivotal REMATCH trial which began enrollment on May 15, 1998 and ended enrollment on July 27, 2001. CMS' 30 month period ended on the day before the publication of our decision to cover destination therapy on October 1, 2003. Our goal was to obtain an unbiased picture of the status of facilities that might be qualified to perform destination therapy. Only a small number of facilities actually had the opportunity to perform destination therapy, but we believed busy, high quality cardiac surgery programs that were implanting bridge devices in severely ill transplant candidates would likely have the kind of experience necessary to maximize patient survival chances with destination therapy. During the five year period for which data are available, the relocation of surgeons and teams may have failed to properly reflect actual experience available in a particular facility such that a facility with seemingly low volumes may have recently integrated a seasoned and experienced VAD team as part of their program. We are aware of facilities that did not qualify for Medicare approval in 2003 because of such movement. When an experienced team moved to a new facility, their experience at the previous facility could not be counted towards the required 15. Due to the strict time limit established for experience in the existing NCD, we are concerned that hospitals that gained the requisite experience after October 1, 2003 were excluded from obtaining Medicare reimbursement.

The October 2003 volume criteria allowed only experience with VADs to count towards the requirement. It is clear that the device landscape has changed for mechanical circulatory support since the original decision. Two mechanical artificial hearts have received FDA approval (October 2004 (FDA approval letter available at www.fda.gov/cdrh/PDF3/P030011a.pdf) and September 2005 (FDA approval letter available at www.fda.gov/cdrh/pdf4/h040006a.pdf)) and are now on the market and available in select hospitals. While we understand that artificial hearts and VADs are different devices, they do treat a similar patient population in that the patients are critically ill with end stage heart failure and are in need of mechanical circulatory support. We believe that it is appropriate for experience implanting artificial hearts to count towards the required volume.

Criteria for facility professional staff

CMS approval criteria were developed with input from the investigators involved with the pivotal REMATCH trial to assure that candidate facilities had current experience both with the treatment of end stage heart failure and a surgical team familiar with long-term support of VAD patients through implantation of VADs as bridge-to-transplant procedures or as a REMATCH participant. At least one facility has demonstrated that an infrastructure of experienced staff can be developed in non-Medicare approved transplant hospitals. CMS did not specify the amount or type of training or board certification status in the approval criteria.

Facility approval process
The coverage decision for destination therapy employed a one-time approval process for facilities that self-certified to meeting volume, staffing and experience criteria and who agreed to report data about destination patients to a national registry. Medicare stipulated no procedure for approving facilities after the initial certification period, nor were there procedures for continuing certification or recertification. Given that experienced surgeons and entire surgical teams occasionally move from one hospital to another, we are concerned that a single entrance requirement is not sufficient to ensure that facilities will continue to meet the necessary experience standards for this technically difficult procedure. In order to ensure good patient outcomes, CMS believes that continued evaluation of procedure volume is critical to ensuring that only appropriate facilities become and remain Medicare approved. We did state in our previous decision memorandum that we expected to establish another process for reviewing and approving facilities and that destination therapy would continue to be considered reasonable and necessary only when provided at a facility that had been evaluated and determined to be qualified to provide this procedure.

2. Evaluation of Joint Commission's Disease Specific Certification Standards dated October 18, 2006 (amended February 2007)

Following the publication of the destination therapy decision on October 1, 2003, the Joint Commission approached CMS about the development of a disease specific certification program for destination therapy similar to that which was implemented for facilities providing Lung Volume Reduction Surgery (see Medicare National Coverage Determination Manual §240.1).

The proposal submitted to CMS for VAD certification was developed within the framework common to all the disease-specific certification programs offered by the Joint Commission. It contains a core set of standards and corresponding elements of performance for each standard applicable to the individual condition of interest, for example, stroke or asthma. Elements of performance are measurable characteristics used to evaluate compliance with standards and thus inform the Joint Commission's review procedures. Elements of performance specifically required for certification of VAD facilities were incorporated into this framework.

In order to develop the VAD-specific elements of performance in its certification program, the Joint Commission assembled a task force composed of physicians representing the Society of Thoracic Surgeons, the American Association for Thoracic Surgery, the American College of Chest Physicians, and other experts, including cardiothoracic surgeons. These experts provided their views on the characteristics critical to the structure and operation of a program capable of providing appropriate services centered on this procedure as well as on patient inclusion/exclusion criteria.

To obtain public input, the Joint Commission posted the proposed VAD requirements on its web site and solicited comments directly from over 60,000 individuals enrolled on the Joint Commission ListServ. The comments received were incorporated where appropriate. The standards were reviewed again by the expert panel before a final VAD certification program proposal was submitted to CMS.

The VAD certification program involves a two-year award cycle with an off-site and an on-site evaluation in the first year and an off-site intra-cycle evaluation during the second year. Certification is limited to hospital-based programs. Review of pre- and post-surgery rehabilitation services is to be conducted as part of the evaluation of the hospital program's ability to provide or coordinate all required services. The standards and elements of performance developed by the Joint Commission for VAD certification are printed in the "Disease-Specific Care Certification Program for Ventricular Assist Device" and are listed in Appendix B. The standards are analyzed in section VIII of this document.

The Joint Commission submitted updated standards in February 2007 to amend the second footnote in their standards document as it relates to describing VADs that count toward the volume requirement. The footnote previously read, "Acceptable ventricular assist device procedures include placement of long-term devices (those with a FDA indication for use over 30 days) or placement of long-term devices as part of studies for FDA approval." The amended footnote removes the language in parentheses regarding the numbers of days a device is indicated for use. Since this is the only change, there is no further discussion of changes between the October 2006 and February 2007 standards.

3. Professional Society Position Statements

In 2003, the International Society for Heart and Lung Transplantation (ISHLT) published a paper which suggested policies for identifying centers that would qualify for long-term destination therapy implantation programs (available online at a http://www.jhltonline.org/article/PIIS1053249803000731/fulltext accessed 12/15/2006). The ISHLT Board favored the following: “Enforce fulfillment of a minimum set of requirements for training of physicians, surgeons, and other personnel and infrastructure, before initiating long-term MCSD [mechanical circulatory support device] programs in all interested centers, with assessment of center-specific outcomes on an annual basis and continued approval based on achieving target outcomes. Rationale: Fulfilling a set of minimum requirements (defined below) will maximize the likelihood of satisfactory performance and outcomes, balanced with the goal of disseminating the new therapy for the benefit of the large AHF [advanced heart failure] population not eligible for heart transplantation.”

ISHLT suggested that at least some of a destination therapy facility’s cardiologists should have, at a minimum, experience in providing long-term care to 10 or more patients with ESHF, but did not stipulate a period of time over which the experience should have been gained. At least one surgeon should have had the lead in implanting “at least 10 mechanical circulatory support devices which have the potential for chronic (>2 months) support and patient ambulation”. They made no suggestion as to the length of time over which this surgical experience should have been gained.

4. Public Comments

Public comment sometimes cites published clinical evidence and gives CMS useful information. Public comments that give information on unpublished evidence such as the results of individual practitioners or patients are less rigorous and therefore, less useful for making a coverage determination. CMS uses the initial public comments to inform its proposed decision. CMS responds in detail to the public comments on a proposed decision when issuing the final decision memorandum.

Initial 30-day public comment period

CMS received 12 comments during the initial 30-day public comment period. The comments are summarized below.

Physician experience (standard DF.1)
One commenter stressed the importance of surgeons having experience with VADs approved for long-term use stating that such experience makes them more familiar with those types of pumps and that the experience makes them better able to determine the length of support that a patient may need. Another commenter, however, supported that experience with short-term VADs (e.g. devices approved for temporary use until the heart regains function or post-cardiotomy) should count toward the surgeon's experience. A third comment on physician experience stated that managing transplant patients should not substitute for experience in managing VAD patients. Two commenters suggested that overall facility competency and the skill of the entire patient care team should be considered.

Four commenters disagreed that board certification should be a requirement. Two commenters suggested that the language be changed to include surgeons with the foreign equivalent of board certification while other commenters suggested that physician experience, volume and teaching should be considered.

Three commenters discussed the minimum number of procedures required for the surgeon. Commenters varied in their opinions with one who agreed that 10 is appropriate and suggested that low volumes lead to poor patient outcomes and the other two disagreed with the use of any fixed number citing the arbitrary nature of selecting such number and that high volumes do not necessarily lead to good outcomes. One of the commenters recommended that the Joint Commission incorporate an exception mechanism by which additional factors could be considered in place of volume. A fourth commenter suggested that outcomes measures are more appropriate than volumes.

Time needed for certification of currently approved facilities
One commenter suggested that currently approved facilities be given 36 months to become certified by the Joint Commission due to the time involved in the certification process and the volume of facilities that would undergo certification.

Patient selection
Four commenters encouraged the removal of patient selection criteria from the Joint Commission standards. The commenters stated that Medicare criteria were already in place, therefore, repeating or altering criteria is repetitive and unnecessary. One commenter expressed concern over the determination of transplant ineligibility stating that it was unclear who needed to make that determination. The same commenter recommended that a Medicare approved transplant facility make the determination initially, but that when the VAD center became comfortable with the criteria for transplant eligibility that it should then be responsible for making future eligibility determinations.

Facility eligibility criteria
Two commenters stated that registry reporting of device implantations that are part of an FDA Investigational Device Exemption (IDE) trial should be optional. The commenters were concerned that data regarding those devices would already be collected as part of the trial and that the data itself is confidential. Another commenter suggested that the eligibility requirements should include status as an approved transplant facility.

Overall comments on standards
One commenter stated that the Joint Commission standards should not repeat guidelines from CMS or the medical specialty societies but rather should focus on quality and outcomes. Another commenter recommended that the standards be reviewed annually to remain current with best practices.

Comment period for the proposed decision

CMS received comments on the proposed decision from 11 commenters. In general, commenters agreed that CMS should use the Joint Commission credentialing program to approve VAD facilities for destination therapy procedures. Commenters made specific recommendations regarding aspects of the standards the Joint Commission would use for credentialing. Because the Joint Commission has established its own standards, and CMS does not control those private standards, we are not responding to comments seeking changes to the Joint Commission's criteria.

Physician experience
Commenters recommended that foreign board certification should qualify the cardiac surgeon and cardiologist as meeting the Joint Commission board certification standard. The Joint Commission standards do not specify which board is acceptable.

Response: The CMS standards do not require board certification. Rather, this is an example of how the Joint Commission standards are more specific than those previously employed by CMS. Therefore, we have determined that in this area the Joint Commission standards exceed the CMS requirements.

Two commenters agreed that utilizing the most recent 36-month time period is appropriate for counting VAD implantations towards the volume requirement. Commenters stated that this standard ensures that programs and personnel are maintained and that it is appropriate for qualification to be based on recent performance.

Response: CMS agrees with these comments. Both the CMS standards and the Joint Commission standards include this requirement.

One public commenter asked whether a surgeon could count procedures for which he was the assistant surgeon toward the required 10.

Response: CMS responds to this question by clarifying that our intent is to only count procedures for which the surgeon was considered the primary surgeon.

One commenter recommended that all VAD procedures, regardless of FDA labeled indication or intended use of the device, should count toward the surgeon's volume. As an example, the commenter points out that devices indicated for bridge to recovery have supported patients for more than 30 days and in some cases more than 90 days. This demonstration of longer term support of patients, the commenter states, should serve as appropriate surgeon experience. This commenter also suggests that artificial heart procedures should be reflected in the volume requirement.

Response: CMS is updating their requirement related to the type of experience that can count toward the volume requirement. Based on comments and our review of the product information, CMS agrees that experience with implanting artificial hearts should be counted. We believe the surgical techniques and clinical intent of implantation (e.g., long-term plan for supporting the patient, potential for patient discharge, etc.) and the complicated issues around patient selection are somewhat similar to dealing with VADs for bridge to transplant or destination therapy patients. In addition, the devices on the market are currently FDA approved for bridge to transplantation or destination therapy as opposed to short term uses. CMS does not agree to allow VADs implanted for any indication to count towards the required volume. Even though short-term use VADs may have the capability of sustaining a patient for longer periods of time, they are not approved for bridge to transplant or destination therapy and we are not aware of published studies regarding such uses.

Some commenters were interested in incorporating outcomes measures in addition to the other requirements. One commenter suggested that certification should also be based on survival, complication and discharge rates and quality of life measures. Other commenters suggested that the INTERMACS registry should serve as the appropriate source for defining acceptable outcomes standards.

Response: The CMS standards do not include a requirement for incorporating outcomes measures. CMS believes that currently, it would be inappropriate to establish outcomes measures since we do not yet know where to set a threshold. The volume of data necessary to undertake such a statistical analysis is not yet available. Information published from the INTERMACS registry may, in the future, provide some guidance on establishing outcomes measures.

Time needed for certification of currently approved facilities
The Joint Commission commented that 24 months was adequate time for that organization to process the volume of facilities that would seek certification.

Response: CMS agrees that this time frame is adequate and we will not require Joint Commission certification until 24 months past the date of this decision. We should be clear that facilities that become Joint Commission certified prior to the 24 month time frame will be added to the CMS approved list at the time they receive certification.

Patient selection
Three commenters made statements about patient selection. Concern was expressed that non-transplant hospitals should not make determinations of a patient's ineligibility for cardiac transplantation.

Response: CMS agrees that such determinations by non-transplant hospitals would be concerning. A transplant hospital should determine the transplant candidacy status of a patient. The Joint Commission standards do not go into explicit detail. We believe that only a transplant hospital can determine transplant eligibility or ineligibility. CMS agrees with another commenter that documentation of the rationale for the determination of transplant eligibility should be recorded and available for each destination therapy patient.

One commenter implied that hospitals have an incentive to select inappropriate patients for VAD implantation in order to maintain the required implant volumes. The commenter recommended that CMS track implant volumes to monitor consistent use of the devices.

Response: CMS understands that there is always a potential for abuse in any volume oriented policy. While the agency will be monitoring outcomes for implants through claims data and the INTERMACS registry, such abuse of the technology would be unethical and would be expected to have significant negative implications.

Other commenters recommended that the body surface area (BSA) requirement outlined in the Medicare coverage policy for destination therapy be changed to allow more flexibility in patient selection.

Response: We do not believe a more flexible standard is appropriate at the present time. We will consider a request to reconsider the NCD if additional devices are FDA approved in the future.

Facility eligibility criteria

Five commenters were concerned that non-transplant centers are eligible to become certified under the Joint Commission standards. Two commenters were adamantly opposed and maintained that only a transplant center could responsibly evaluate patients and utilize the technology. The other commenters support strong, formal relationships between non-transplant and transplant hospitals since some patients implanted for destination therapy may in some circumstances recover enough to become transplant candidates and because of the importance of appropriate patient selection.

Response: CMS supports relationships between non-transplant and transplant hospitals for purposes of evaluating the patient's transplant candidacy continuously in the event his condition improves so that he becomes transplant eligible. The original CMS standards from the 2003 decision allowed non-transplant centers to apply for approval under an exception. Exception status was granted to one non-transplant hospital that demonstrated its outcomes were as good as some transplant facilities. CMS expects the Joint Commission to maintain a high level of scrutiny when evaluating all facilities to ensure that both transplant and non-transplant hospitals have the appropriate infrastructure including staff, facilities, training, processes and equipment to successfully maintain a VAD destination therapy program. CMS believes that eliminating facilities on the sole basis of not being a transplant hospital is inappropriate; rather, they should be evaluated to ensure that they have the appropriate infrastructure.

Two commenters addressed the requirement of registry participation. Both were in favor of the requirement but recommended that INTERMACS be the required registry. Further, there were recommendations to include devices implanted as part of investigational device exemption (IDE) trials, using registry data to establish acceptable outcomes criteria and for CMS to receive registry generated reports more often than once per year.

Response: CMS has taken this comment under advisement and, now that the Mechanical Circulatory Support Device registry has closed, will specifically require that INTERMACS (currently as the only available registry) be the registry that satisfies the CMS reporting requirement. The issue regarding the submission of IDE and clinical trial data is one that must be worked out between industry and INTERMACS. Regarding using INTERMACS data to establish outcomes thresholds, CMS agrees that INTERMACS data may be useful in the future for industry, professionals and the Joint Commission to establish such thresholds. Currently however, the data are not robust enough to incorporate outcome-based standards into policy.

Three commenters stated that the Joint Commission should incorporate an exception process to account for facilities that do not meet the standards. One of the recommendations was to allow lower volume facilities to be reviewed on the basis of outcomes, geographic location and the patient population.

Response: CMS established an exception process in the 2003 policy for hospitals that did not meet the 15 implantation volume or were not transplant facilities. Few exceptions were made. However, there were no facilities approved under the exception process with fewer than 10 implants. Since with this decision CMS is changing the facility standards to allow 10 as the minimum volume requirement, there is no longer a need for an exception process for volume. In addition, the agency also modified the facility standards to allow non-transplant facilities to qualify if they have the appropriate infrastructure and therefore, have eliminated the need for an exception based on a facility's transplant status.

Overall comments on standards
Most commenters agreed that Joint Commission evaluation and credentialing in this clinical area is appropriate. One commenter stated that the Joint Commission standards should be updated annually to keep up with clinical guidelines.

Response: The CMS has evaluated the Joint Commission credentialing program based on the February 2007 standards (Appendix B). While the Joint Commission may have internal processes of evaluating their standards, in order for updated standards to maintain CMS approval they would need to be reviewed by the agency. At this time, CMS is recognizing only the Joint Commission standards dated February 2007.

VIII. CMS Analysis

National coverage determinations (NCDs) are determinations by the Secretary with respect to whether or not a particular item or service is covered nationally under title XVIII of the Social Security Act § 1869(f)(1)(B). In order to be covered by Medicare, an item or service must fall within one or more benefit categories contained within Part A or Part B, and must not be otherwise excluded from coverage. Moreover, with limited exceptions, the expenses incurred for items or services must be "reasonable and necessary for the diagnosis or treatment of illness or injury or to improve the functioning of a malformed body member." § 1862(a)(1)(A).

We previously concluded that VAD destination therapy was reasonable and necessary for certain patients meeting specific criteria if performed in certain qualified facilities. We have been asked to modify this NCD to permit coverage in facilities that meet alternative standards. Except as noted below, all other aspects of the existing NCD remain unchanged.

- Should CMS modify its facility criteria for ventricular assist devices as destination therapy?

CMS has considered the facility criteria and identified five areas which require modification: 1) volume criteria; 2) interval for measuring the volume requirement; 3) the requirement that hospitals be Medicare-approved heart transplant facility; 4) the opportunity for an exception to these criteria; and 5) that the facility participate in INTERMACS for reporting destination therapy VADs.

Previously, Medicare required that, “between January 1, 2001, and September 30, 2003, [facilities] implanted at least 15 VADs as a bridge-to-transplant or as destination therapy.” However, CMS granted an exception for 12 facilities that did not meet the volume requirement of 15. We believe that a requirement to have implanted at least 10 VADs as bridge-to-transplant or as destination therapy during a 3-year period is more appropriate, is consistent with professional society standards, and is similar to the exception criteria that were established in the October 2003 decision. Based on the limited data available from the MCSD for implants between 2003 and 2005, we did not identify significant differences in outcomes between facilities that had experience with 10-15 implants compared to those with greater than 15 implants. We do not believe that experience with less than 10 is sufficient to ensure good outcomes. Numbers below 10 make it very difficult to evaluate the consistency of good outcomes and due to the technically demanding nature we feel that experience contributes to good outcomes.

The range of available circulatory support devices has expanded since 2003 with the introduction of artificial hearts to the market beginning in October 2004. While these devices have narrow approvals from the FDA, they are available in select hospitals. Artificial hearts often serve a patient population similar to that served by VADs in that the patients are critically ill with end stage heart failure. The implantation of artificial hearts is a technically demanding procedure that requires a team approach to care for the critically ill, an infrastructure prepared to handle patients that will require long-term device support as well as support to patients and families upon discharge. Although not currently covered under Medicare, CMS will change their criteria to allow experience with artificial hearts to count towards the volume requirement.

We are concerned that our existing NCD which included a strict time limit for the requisite volume experience (ending September 30, 2003), effectively discourages new hospitals from seeking the requisite experience that would enable the hospital to obtain Medicare reimbursement. Given the greater experience with VAD as destination therapy, including our experience with hospitals that have performed well under the existing exception process, we are eliminating the September 30, 2003 deadline, in favor of a more flexible 3-year time period. This continuous measurement of volume ensures that facilities maintain currency with this technically demanding surgical procedure.

Facility approval for heart transplants by Medicare was used in the October 2003 decision to assure that the proper infrastructure was in place to care for these patients. However, since at least one facility demonstrated that such an infrastructure can exist in the absence of a transplant program, Medicare is proposing to remove this requirement and allow non-transplant facilities to be approved when they meet the facility criteria in this NCD. This indicates to us that being a transplant facility is not the only way to gain the expertise and supporting structure to perform the procedure successfully.

In October 2003, Medicare allowed for an exception to the volume and transplant status requirements. One non-Medicare approved transplant facility was approved through this process and multiple facilities were approved even though their volumes were less than 15. Since Medicare is proposing to lower the volume requirement to 10 and remove the transplant status requirement, the exception process is no longer necessary and can be eliminated.

CMS believes that performance of 10 procedures over a three year period and ongoing re-evaluation of procedure volume at specified intervals are appropriate standards for initial and ongoing approval of a facility to perform these technically demanding procedures. In order to ensure that previously approved facilities continue to maintain expertise, CMS will allow third-party entities to evaluate and re-evaluate VAD destination therapy facilities when using standards evaluated and approved by Medicare to meet the established minimum standards. CMS will evaluate the standards proposed by third-party entities that have the capability to perform such credentialing services.

The 2003 decision names the MCSD as the registry available for hospitals to report destination therapy VADs. The MSCD has since been superseded by INTERMACS. Therefore, we are updating the policy to name INTERMACS as the appropriate registry. CMS will use these data to ensure that destination therapy is provided to appropriate patients in the manner described in the NCD. CMS will receive summary reports regarding the volume of implantations and clinical conditions related to the Medicare coverage criteria in participating hospitals (e.g., ejection fraction). CMS will determine if the care provided in that facility meets the clinical indications for Medicare coverage.

- Are the Joint Commission standards, dated February 2007, at least equivalent to the CMS standards used to select facilities for ventricular assist devices as destination therapy?

The new Joint Commission program does not limit certification to transplant facilities, but provides other standards for measurement of quality of care, which we believe will assure that only fully qualified facilities will be approved. CMS has approved facilities other than heart transplant facilities based upon an exception process. The Joint Commission standards include an assessment of adequate staffing and facilities for the procedure and to care for patients post-procedure.

The Joint Commission criteria include standards requiring facilities to participate in a national, audited registry which we have identified as INTERMACS. Therefore, this requirement is equal to the CMS facility requirement regarding INTERMACS participation.

The Joint Commission certification requirement for facilities to be approved to provide destination therapy requires that the facility's surgical team must have implanted 10 ventricular assist devices for long-term use over a three year period, the Joint Commission standard allows for the inclusion of some artificial heart implantations to count towards the volume requirement. Therefore, the volume standards in the Joint Commission requirements meet the CMS volume requirement.

The Joint Commission certification criteria for professional personnel managing destination patients require that one or more of the cardiologists on the team be board certified; have experience in treatment of advanced heart failure and recent experience in managing VAD or transplant patients; and have gained competence to evaluate patients for transplant through work at a transplant center. The destination therapy team must also include one or more board certified cardiac surgeons, who have successfully placed 10 long-term VADs in the last 36 months with current activity in the last year.

CMS has determined that these somewhat more explicit personnel requirements will assure that facilities approved to provide destination therapy under Joint Commission criteria will continue to provide the high quality care and meet or exceed the personnel standards for Medicare heart transplant centers. Since CMS proposes that being a transplant center would no longer be required to be approved as a VAD destination therapy facility, it is appropriate that more explicit criteria be put in place to ensure that the facility has the appropriate personnel. Therefore, the personnel requirements in the Joint Commission standards meet and in some cases are more explicit and exceed the CMS requirements.

We believe the Joint Commission certification criteria offer assurance that a facility meeting them will be able to perform well the technically demanding surgical procedure for proper device implantation, post-operative care and long-term patient management. Not only do we believe that the Joint Commission standards are equivalent to the CMS standards, but we believe there are some significant additional benefits. The Joint Commission has incorporated specific performance measures and quality improvement requirements in its certification processes. The Joint Commission has also incorporated outcome measures. In addition, the certification program has a mechanism for facility re-approval. Adoption of this certification program by Medicare would permit additional facilities to qualify as providers of destination therapy and will provide a means to assure that previously certified facilities continue to meet certification standards. We will continue to update our website with information from the Joint Commission as to certification status, including any terminations which may occur.

After detailed comparison of the Joint Commission's "Disease-Specific Care Certification Program for Ventricular Assist Device" standards to the updated CMS facility criteria, we have concluded that the Joint Commission standards are at least equivalent to the CMS standards. Therefore, we propose that facilities meeting those standards will be approved to provide destination therapy. Facilities currently approved under the October 2003 NCD will have 24 months to seek Joint Commission certification. Facilities that do not certify through the Joint Commission by that date will be removed from the approval list maintained on the CMS website. Adoption of the Joint Commission standards and methods will offer an opportunity for certification to any hospital that possesses the competence required to implant VADs for destination therapy successfully. Should the Joint Commission change their standards, the new standards will not be automatically approved by CMS. In that event, the Joint Commission certification program would need to be reevaluated by CMS. Any facilities certified under altered standards, not approved by CMS, would not be eligible for payment for VADs implanted in Medicare beneficiaries.

Issuance of this decision updates the facility criteria published in the 2003 decision under which 69 hospitals were previously approved. In order to ensure that these facilities meet the updated criteria each facility will be required to supply CMS with documentation related to the updated criteria. In spring 2007, CMS will send a request letter to each previously approved facility specifying the information that must be included in the hospital's response. They will be asked to demonstrate that: a) at least one surgeon on their VAD team has implanted at least 10 VADs and/or artificial hearts over the most recent 36 months; and b) the facility is participating in the Interagency Registry for Mechanically Assisted Circulatory Support (INTERMACS).

Facilities must demonstrate that they meet the updated criteria in order to remain Medicare approved for destination therapy VAD implantation. CMS will not accept applications from facilities other than the 69 already approved. Those not currently on the approved list have the opportunity to become approved at any time through certification by the Joint Commission.

IX. Decision

A. Summary of changes

The Centers for Medicare and Medicaid Services (CMS) modifies the facility criteria for Ventricular Assist Device (VAD) implantation as destination therapy as follows:

- Reducing the VAD implant volume standard from 15 VADs to 10 VADs or artificial hearts implanted over a three year period either as bridge-to-transplant or as destination therapy;
- The facility's VAD team must include a surgeon with the requisite volume;
- Changing the volume measurement period from January 1, 2001 through September 30, 2003 to a continuous 3-year period;
- Eliminating the requirement that the hospital must be a Medicare-approved heart transplant facility;
- Eliminating the opportunity for an exception to these standards;
- Naming the Interagency Registry for Mechanically Assisted Circulatory Support (INTERMACS) as the registry that satisfies the CMS reporting requirement;
- Requiring that facilities be approved under the "Disease-Specific Care Certification Program for Ventricular Assist Device" developed by the Joint Commission on Accreditation of Healthcare Organizations, dated February 2007, and establishing a time limit for existing facilities to complete this process; and
- Requiring current facilities to document their continued compliance with the current and modified requirements outlined in this NCD.

B. Updated NCD Manual section 20.9 (changes are italicized)

20.9 - Artificial Hearts and Related Devices - *Effective March 27, 2007 (Rev.)*

A. General

A ventricular assist device (VAD) or left ventricular assist device (LVAD) is used to assist a damaged or weakened heart in pumping blood. These devices are used for support of blood circulation post-cardiotomy, as a bridge to a heart transplant, or as destination therapy.

B. Nationally Covered Indications

1. Postcardiotomy (effective for services performed on or after October 18, 1993)
Post-cardiotomy is the period following open-heart surgery. VADs used for support of blood circulation post-cardiotomy are covered only if they have received approval from the Food and Drug Administration (FDA) for that purpose, and the VADs are used according to the FDA- approved labeling instructions.

2. Bridge-to-Transplant (effective for services performed on or after January 22, 1996)
The VADs used for bridge-to-transplant are covered only if they have received approval from the FDA for that purpose, and the VADs are used according to the FDA-approved labeling instructions. All of the following criteria must be fulfilled in order for Medicare coverage to be provided for a VAD used as a bridge-to-transplant:

a. The patient is approved and listed as a candidate for heart transplantation by a Medicare-approved heart transplant center; and

b. The implanting site, if different than the Medicare-approved transplant center, must receive written permission from the Medicare-approved heart transplant center under which the patient is listed prior to implantation of the VAD.

The Medicare-approved heart transplant center should make every reasonable effort to transplant patients on such devices as soon as medically reasonable. Ideally, the Medicare-approved heart transplant centers should determine patient-specific timetables for transplantation, and should not maintain such patients on VADs if suitable hearts become available.

3. Destination Therapy (effective for services performed on or after October 1, 2003 *with facility criteria updated March 27, 2007*)
Destination therapy is for patients that require permanent mechanical cardiac support. The VADs used for destination therapy are covered only if they have received approval from the FDA for that purpose, and the device is used according to the FDA-approved labeling instructions.

Patient Selection
VADs are covered for patients who have chronic end-stage heart failure (New York Heart Association Class IV end-stage left ventricular failure for at least 90 days with a life expectancy of less than 2 years), are not candidates for heart transplantation, and meet all of the following conditions:

a. The patient's Class IV heart failure symptoms have failed to respond to optimal medical management, including dietary salt restriction, diuretics, digitalis, beta-blockers, and ACE inhibitors (if tolerated) for at least 60 of the last 90 days;
b. The patient has a left ventricular ejection fraction (LVEF) < 25%;
c. The patient has demonstrated functional limitation with a peak oxygen consumption of < 12 ml/kg/min; or the patient has a continued need for intravenous inotropic therapy owing to symptomatic hypotension, decreasing renal function, or worsening pulmonary congestion; and,
d. The patient has the appropriate body size (≥ 1.5 m^2) to support the VAD implantation.

Facility Criteria (effective March 27, 2007)
a. Facilities must have at least one member of the VAD team with experience implanting at least 10 VADs (as bridge to transplant or destination therapy) or artificial hearts over the course of the previous 36 months;

b. Facilities must be a member of the Interagency Registry for Mechanically Assisted Circulatory Support (INTERMACS); and
c. By 3/27/09 all facilities must meet the above facility criteria and be credential by the Joint Commission under the Disease Specific Certification Program for Ventricular Assist Devices (standards dated February 2007).

The website http://www.cms.hhs.gov/MedicareApprovedFacilitie/VAD/list.asp#TopOfPage will be updated continuously to list all approved facilities. Facilities gaining Joint Commission certification (including prior to 3/27/09) will be added to the website when certification is obtained.

Hospitals also must have in place staff and procedures that ensure that prospective VAD recipients receive all information necessary to assist them in giving appropriate informed consent for the procedure so that they and their families are fully aware of the aftercare requirements and potential limitations, as well as benefits, following VAD implantation.

C. Nationally Non-Covered Indications (effective for services performed on or after May 19, 1986)

1. Artificial Heart
Since there is no authoritative evidence substantiating the safety and effectiveness of a VAD used as a replacement for the human heart, Medicare does not cover this device when used as an artificial heart.

2. All other indications for the use of VADs not otherwise listed remain noncovered, except in the context of Category B IDE clinical trials (42 CFR 405) or as a routine cost in clinical trials defined under section 310.1 of the NCD manual (old CIM 30-1).

Appendix A

National Coverage Determination Manual 100-03
Artificial Hearts and Related Devices (20.9)
Old Policy (effective October 1, 2003-March 26, 2007)

20.9 - Artificial Hearts And Related Devices
(Rev. 2, 10-17-03)

A ventricular assist device (VAD) or left ventricular assist device (LVAD) is used to assist a damaged or weakened heart in pumping blood. These devices are used for support of blood circulation post-cardiotomy, as a bridge to a heart transplant, or as destination therapy.

A. Covered Indications

1. Postcardiotomy (effective for services performed on or after October 18, 1993)

Post-cardiotomy is the period following open-heart surgery. VADs used for support of blood circulation post-cardiotomy are covered only if they have received approval from the Food and Drug Administration (FDA) for that purpose, and the VADs are used according to the FDA- approved labeling instructions.

2. Bridge-to-Transplant (effective for services performed on or after January 22, 1996)

The VADs used for bridge-to-transplant are covered only if they have received approval from the FDA for that purpose, and the VADs are used according to the FDA-approved labeling instructions. All of the following criteria must be fulfilled in order for Medicare coverage to be provided for a VAD used as a bridge-to-transplant:

a. The patient is approved and listed as a candidate for heart transplantation by a Medicare-approved heart transplant center; and

b. The implanting site, if different than the Medicare-approved transplant center, must receive written permission from the Medicare-approved heart transplant center under which the patient is listed prior to implantation of the VAD.

The Medicare-approved heart transplant center should make every reasonable effort to transplant patients on such devices as soon as medically reasonable. Ideally, the Medicare-approved heart transplant centers should determine patient-specific timetables for transplantation, and should not maintain such patients on VADs if suitable hearts become available.

3. Destination Therapy (effective for services performed on or after October 1, 2003)

Destination therapy is for patients that require permanent mechanical cardiac support. The VADs used for destination therapy are covered only if they have received approval from the FDA for that purpose, and the device is used according to the FDA-approved labeling instructions. VADs are covered for patients who have chronic end-stage heart failure (New York Heart Association Class IV end-stage left ventricular failure for at least 90 days with a life expectancy of less than 2 years), are not candidates for heart transplantation, and meet all of the following conditions:

a. The patient's Class IV heart failure symptoms have failed to respond to optimal medical management, including dietary salt restriction, diuretics, digitalis, beta-blockers, and ACE inhibitors (if tolerated) for at least 60 of the last 90 days;

b. The patient has a left ventricular ejection fraction (LVEF) < 25%;

c. The patient has demonstrated functional limitation with a peak oxygen consumption of < 12 ml/kg/min; or the patient has a continued need for intravenous inotropic therapy owing to symptomatic hypotension, decreasing renal function, or worsening pulmonary congestion; and,

d. The patient has the appropriate body size (≥; 1.5 m^2) to support the VAD implantation.

In addition, the Centers for Medicare & Medicaid Services (CMS) has determined that VAD implantation as destination therapy is reasonable and necessary only when the procedure is performed in a Medicare-approved heart transplant facility that, between January 1, 2001, and September 30, 2003, implanted at least 15 VADs as a bridge-to-transplant or as destination therapy. These devices must have been approved by the FDA for destination therapy or as a bridge-to-transplant, or have been implanted as part of an FDA investigational device exemption (IDE) trial for one of these two indications.

The VADs implanted for other investigational indications or for support of blood circulation post-cardiotomy do not satisfy the volume requirement for this purpose. Since the relationship between volume and outcomes has not been well-established for VAD use, facilities that have minimal deficiencies in meeting this standard may apply and include a request for an exception based upon additional factors. Some of the factors CMS will consider are geographic location of the center, number of destination procedures performed, and patient outcomes from VAD procedures completed.

Also, this facility must be an active, continuous member of a national, audited registry that requires submission of health data on all VAD destination therapy patients from the date of implantation throughout the remainder of their lives. This registry must have the ability to accommodate data related to any device approved by the FDA for destination therapy regardless of manufacturer. The registry must also provide such routine reports as may be specified by CMS, and must have standards for data quality and timeliness of data submissions such that hospitals failing to meet them will be removed from membership. The CMS believes that the registry sponsored by the International Society for Heart and Lung Transplantation is an example of a registry that meets these characteristics.

Hospitals also must have in place staff and procedures that ensure that prospective VAD recipients receive all information necessary to assist them in giving appropriate informed consent for the procedure so that they and their families are fully aware of the aftercare requirements and potential limitations, as well as benefits, following VAD implantation.

The CMS plans to develop accreditation standards for facilities that implant VADs and, when implemented, VAD implantation will be considered reasonable and necessary only at accredited facilities.

A list of facilities eligible for Medicare reimbursement for VADs as destination therapy will be maintained on our Web site and available at www.cms.hhs.gov/coverage/lvadfacility.asp. In order to be placed on this list, facilities must submit a letter to the Director, Coverage and Analysis Group, 7500 Security Blvd, Mailstop C1-09-06, Baltimore, MD 21244. This letter must be received by CMS within 90 days of the issue date on this transmittal. The letter must include the following information: Facility’s name and complete address;

- Facility's Medicare provider number;
- List of all implantations between Jan. 1, 2001, and Sept. 30, 2003, with the following information:
    - Date of implantation,
    - Indication for implantation (only destination and bridge-to-transplant can be reported; post-cardiotomy VAD implants are not to be included),
    - Device name and manufacturer, and
    - Date of device removal and reason (e.g., transplantation, recovery, device malfunction), or date and cause of patient's death;
- Point-of-contact for questions with telephone number;
- Registry to which patient information will be submitted; and,
- Signature of a senior facility administrative official.

Facilities not meeting the minimal standards and requesting exception should, in addition to supplying the information above, include the factors that they deem critical in requesting the exception to the standards.

The CMS will review the information contained in the above letters. When the review is complete, all necessary information is received, and criteria are met, CMS will include the name of the newly Medicare-approved facility on the CMS Web site. No reimbursement for destination therapy will be made for implantations performed before the date the facility is added to the CMS Web site. Each newly approved facility will also receive a formal letter from CMS stating the official approval date it was added to the list.

B. Noncovered Indications (effective for services performed on or after May 19, 1986)

1. Artificial Heart

Since there is no authoritative evidence substantiating the safety and effectiveness of a VAD used as a replacement for the human heart, Medicare does not cover this device when used as an artificial heart.

2. All other indications for the use of VADs not otherwise listed remain noncovered, except in the context of Category B IDE clinical trials (42 CFR 405) or as a routine cost in clinical trials defined under section 310.1 of the NCD manual (old CIM 30-1).

Appendix B

Joint Commission Disease-Specific Certification Program
VENTRICULAR ASSIST DEVICE DESTINATION THERAPY CERTIFICATION
FINAL RECOMMENDATIONS
February 2007

The chart below contains existing Disease Specific Care standards and the elements of performance used to evaluate compliance with those standards. Any program applying for Disease Specific Certification must meet all the applicable standards in the program. There are nine elements of performance that have requirements specific for Ventricular Assist Device Destination Therapy Programs.

Standard	**Element of Performance**/ *Requirement Specific to Ventricular Assist Device Destination Therapy Certification*
Eligibility Criteria	

		Facilities have infrastructure to support ventricular assist device placements as evidenced by adequate staffing and facilities to perform and recover patients after cardiac surgery. *Programs must be an active continuous member of a national, audited registry for mechanically assisted circulatory support devices[1], that requires submission of health data on ventricular assist device destination therapy patients from the date of implantation throughout the remainder of their lives.*
Delivering or Facilitating Clinical Care (DF)		
DF.1 Practitioners are qualified and competent.	1	Practitioners have educational backgrounds, experience, training, and/or certification consistent with the program's mission, goals, and objectives. *Physicians managing the patient include but are not limited to:* *One or more board-certified cardiologists each of whom:* • *Is trained and experienced in advanced heart failure therapies,* • *Has had recent experience managing patients who have had ventricular assist devices placed or heart transplants, and* • *Has sufficient competency in evaluating patients for transplant as evidenced by having worked in or trained in a transplant center.* *One or more board certified cardiac surgeons each of whom:* • *Has successfully placed ten (10) ventricular assist devices[2] in the last 36 months with current activity in the last year.*
	2	Core criteria for hiring practitioners in the program include, at a minimum, current licensure, relevant education, training and experience, and current competence.

	3	Criteria for evaluating practitioners in the program include, at a minimum, current licensure and current competence.
	4	Current licensure is verified from primary sources.
	5	Orientation provides information and necessary training appropriate to program responsibilities.
	6	The competence of all practitioners is assessed when new techniques or responsibilities are introduced and periodically within the timeframes defined by the program.
	7	Ongoing in-service and other education and training activities are relevant to the program's needs.
	8	Practice, care, and/or services are analyzed for negative patterns and trends to provide feedback to practitioners and to identify and respond to their learning needs.
	1	The CPGs used are based on evidence that has been evaluated as current by the clinical leaders.

DF.2 A standardized process originating in clinical practice guidelines [CPGs] or evidence-based practice is used to deliver or facilitate the delivery of clinical care.	2	The CPGs used have been evaluated as appropriate for the target population.
	3	When the CPGs are selected by a sponsoring organization (for example, a disease management service provider uses a CPG chosen by the health plan with which it contracts), the program evaluates the CPGs to ensure that they are appropriate for their intended use.
	4	*Assessment activities are consistent with CPGs.* *Acceptance criteria:* • *Patients who have an anticipated survival benefit.* • *Patients with NYHA Class IV heart failure symptoms that have failed to respond to optimal medical management.* • *Patients with a demonstrated functional limitation with a peak oxygen consumption of ≤ 14 ml/kg/min.* • *Patients with a continued need for intravenous inotropic therapy.* • *Patients who have been evaluated for heart transplant and were not selected as candidates* • *NOTE: To receive CMS reimbursement, patients must meet current CMS patient selection and coverage criteria.*
	5	Intervention activities are consistent with CPGs.
	6	Adapted or adopted CPGs are reviewed annually or when significant changes in the field occur, to ensure their appropriateness for the program.
	7	Modifications made to CPGs are implemented.

	8	Appropriate leaders and practitioners in the program review and approve CPGs selected for implementation.
	9	Practitioners have been educated about CPGs and their use.
DF.3 The standardized process is tailored to meet the participant's needs.	1	The program defines the patient assessment process.
	2	An assessment is completed for all participants within the time frame determined by the program.
	3	The assessment is used to develop a plan of care.
	4	An explicit method of stratification exists.
	5	Stratification methods direct interventions.

	6	The standardized method or process is tailored to meet the targeted population's age and developmental needs.
	7	The plan of care is updated to meet the participant's ongoing needs.
DF.4 Concurrently occurring conditions are managed, or the information necessary for their management is communicated to the appropriate practitioner(s).	1	Care is coordinated for participants with multiple diseases and/or whom multiple disease-specific care programs manage. *Coordination of care of the patients is conducted in part at a regularly scheduled ventricular assist device meeting that is attended by the scope of disciplines involved in the care of the patients.*
	2	When concurrently occurring conditions are identified, salient information is communicated to the appropriate practitioners treating or managing the condition(s).
	3	When a concurrently occurring condition needs medical intervention, the patient is either treated by the practitioners in the program or referred to an appropriate practitioner.
	4	The program has a mechanism for managing urgent health issues. *Members of the team are available to other practitioners managing the patient as needed even after discharge from the program.*

DF.5 The standardized process is revised or improved through the ongoing collection and evaluation of data regarding variance from the clinical practice guideline.	1	Variances are tracked at the individual participant level.
	2	Use of the CPGs is modified based on the analysis of outcomes.
	3	Information related to the changes made within the standardized process is communicated to all appropriate individuals.
	4	Changes in the standardized process are evaluated.
Performance Measurement and Improvement (PM)		
PM.1 The program has an organized, comprehensive approach to performance improvement [PI].	1	The PI program is well designed and planned.
	2	The PI program collects relevant data.
	3	The PI program analyzes current performance.

	4	The PI program improves and sustains performance.
	5	PI activities are planned across practitioners, disciplines, and/or settings.
	6	PI activities include input from participants.
PM.2 The program uses measurement data to evaluate process and outcomes.	1	The program selects performance measures that are the following: • Based on the clinical practice guideline or other evidence • Relevant to the management of the disease • Valid • Reliable
	2	Data related to processes and/or outcomes of care are collected at the level of the individual participant.
	3	The program reports data aggregated at the program level to the Joint Commission on Accreditation of Healthcare Organizations at the defined intervals. • *Survival rate (All cause mortality)* • *Functional capacity*

		• *Any results provided by the national registry.*
	4	Measurement data are analyzed.
	5	Measurement data are used to improve processes and outcomes.
PM.3 Participant perception of care quality is evaluated.	1	The program evaluates participant perception of care quality.
	2	The program makes improvements based on the analysis of the feedback from participants about the perception of care quality.
PM.4 Data quality and integrity are maintained.	1	Minimum data sets, data definitions, codes, classifications, and terminology are standardized throughout the program.
	2	Data collection is timely, accurate, complete, and sufficiently discriminating for its intended use throughout the program.
	3	The program monitors data reliability (including accuracy and completeness) and validity on an ongoing basis and verifies that data bias is minimized.

	4	Sampling methodology is based on measurement principles.
	5	Appropriate data analysis tools are used.
	6	Factors (participant and/or practitioner) that might affect the outcome(s) of the process (es) being measured have been evaluated.
Supporting Self-Management (SE)		
SE.1 The program involves participants in making decisions about managing their disease or condition.	1	Participants are involved in decisions about their clinical care. *Signed consent reflects the patient's awareness of preoperative, intraoperative, and postoperative plans and expectations*
	2	Participants and practitioners mutually agree upon goals.
	3	Participants are informed of their responsibilities to provide information to facilitate treatment and cooperate with health care practitioners.

	4	Participants are informed about potential consequences of not complying with a recommended treatment.
	5	The patient's readiness, willingness, and ability to provide or support self-management activities are assessed.
	6	As appropriate, the family's readiness, willingness and ability to provide or support self-management activities are assessed.
SE.2 The program addresses lifestyle changes that support self-management regimens.	1	Lifestyle changes that support self-management regimens are promoted as necessary.
	2	Support structures (family and community) are involved as necessary. • *The hospital ascertains that the patient's home situation is satisfactory and that the patient has power supply and telephone services.* • *Psychological support is available for the patient and their families to meet the unique challenges associated with destination ventricular assist device implantation.* • *Communication is sent from the hospital to the power company informing them that a ventricular assist device patient lives in the vicinity.* • *There is a mechanism to provide twenty-four hour, seven day a week support for the patient and family to handle emergency and urgent care following discharge from the hospital.*

	3	Barriers to change are evaluated as necessary.
	4	The participant's response to making the recommended lifestyle changes is assessed and documented.
	5	The effectiveness of efforts to help the participant in making lifestyle changes is assessed.
SE.3 The program addresses participants' education needs.	1	Materials comply with generally recommended elements of intervention in the literature or promoted through the CPGs.
	2	Content is presented in an understandable and culturally sensitive manner.
	3	The participant's comprehension is assessed initially and on an ongoing basis.
	4	Education needs related to lifestyle changes that support self-management regimens are addressed.

	5	Education needs related to health promotion and disease prevention are addressed.
	6	Education needs related to information about the participant's illnesses and treatments are addressed.
	7	When appropriate, participants are notified about screening recommendations or lifestyle changes related to preventing the disease for their family members, that the participant could then present to the family member
Program Management (PR)		
PR.1 Leadership roles in the program are clearly defined.	1	The leaders involved in program development and oversight have educational backgrounds, experience, training, and/or certification consistent with the program's mission, goals, and objectives.
	2	The leaders' accountability is clearly defined.
	3	The leaders participate in designing, implementing, and evaluating care, treatment, and services.

	4	The leaders provide for the uniform performance of patient care, treatment, and services.
	5	The leaders confirm that practitioners practice only within their licensure, training, and current competency.
	6	The leaders set expectations, develop plans, and manage processes to measure, assess, and improve the quality of their leadership and the program's management, clinical, and support activities.
PR.2. The program is relevant for the targeted population and/or health care service areas.	1	The program's mission and scope of services are defined in writing and approved by the appropriate leaders.
	2	The program identifies their target population.
	3	The program ensures that the services available are relevant for its targeted population.
	1	Care, treatment, and services offered are provided to the participants as planned and in a timely manner.

PR.3 The scope and level of care, treatment, and services offered by the program are provided to participants.		
	2	Participants are informed of how to access care and services, including after hours (if applicable). *When the patient will not reside within a reasonable commuting distance from the facility following discharge, the program shall arrange appropriate follow-up care for them with a facility and physician near their residence at the time of discharge.*
	3	Adequate numbers and types of practitioners are available to deliver or facilitate the delivery of care, treatment, and services.
	4	The program evaluates services provided through contractual arrangement to ensure that the scope and level of care, treatment, and services are consistently provided.
	5	Documented policies, processes, and procedures support the care, treatment, and services provided.
PR.4 Eligible patients have access to the care and services provided by the program.	1	Enrollment and/or participation requirements are well defined.
	2	For programs that do not rely solely on direct referrals, a systematic method based on perceived need is used to identify potential participants.

	3	For programs that do not rely solely on direct referrals, individuals are given multiple opportunities to participate in the program.
PR. 5 The scope and level of care, treatment, and services provided are comparable for individuals with the same acuity and type of condition.	1	Individuals have access to an adequate level of resources required to meet the health care needs for the disease(s) being managed.
PR.6. The program's leaders and, as appropriate, participants, practitioners, and community leaders collaborate to design, implement, and evaluate services.	1	All relevant individuals and/or disciplines participate in designing the program.
	2	All relevant individuals and/or disciplines participate in implementing the program.
	3	All relevant individuals and/or disciplines participate in evaluating the program.
PR.7 The program complies with applicable laws and regulations.	1	The program complies with applicable laws and regulations.

PR.8 The program follows a code of ethics.	1	The program protects the integrity of clinical decision-making, regardless of how the program compensates or shares financial risk with its leaders, managers, and practitioners.
	2	The program respects the participant's right to decline participation in the program.
	3	The program provides for receiving and resolving complaints and grievances in a timely way.
PR.9 Facilities where individuals receive care are safe and physically accessible.	1	The program has evaluated security and implemented strategies to minimize security risks.
	2	The program has developed an emergency plan and implemented strategies to minimize the risk of disruption of care due to an environmentally-related emergency.
	3	The program has evaluated risk points in fire safety and implemented strategies to minimize the risk of fire and fire safety-related issues.

	4	The program has developed and implemented a medical equipment management plan.
	5	The program has evaluated risk points in power, gas, and communication services and implemented strategies to minimize those risks.
	6	Staff has learned environment of care risk-reduction strategies.
	7	The program tracks incidents related to the environment of care and makes changes accordingly.
PR.10 The program has reference and resource materials readily available.	1	The program has reference materials (hard copy or electronic) that are easily accessible to practitioners.
	2	The resources are authoritative and current.
PR.11 The process for identifying, reporting, managing, and tracking sentinel events is defined and implemented.	1	A process exists for identifying these events if and when they occur.
	2	

		A process exists for internally tracking these events if and when they occur.
	3	A process exists for analyzing these events if and when they occur.
	4	Changes are made accordingly.
Clinical Information Management (CT)		
CT.1 The confidentiality and security of participant information are preserved.	1	Participant confidentiality is preserved.
	2	Records and information are safeguarded against loss, destruction, tampering, and unauthorized access or use.
	3	Participants and practitioners about whom data and information may be collected are made aware of how the information will be used.
	4	Methods for adding comments in the form of statements or addenda into the formal records are defined.

	5	Individuals and/or positions that have access to information and measures compliance with access limitations are defined.
	6	How and when consent for release of information is required and defined.
	7	Process followed when confidentiality and security are violated is defined.
CT.2 The program gathers information about the participant's disease or condition from practitioners and settings across the continuum of care.	1	The program gathers information directly from the participant and/or family.
	2	Information is gathered from all relevant practitioners or health care organizations. • *The program gathers information from all relevant practitioners or health care organizations prior to implantation of the ventricular assist device.* • *The program gathers information from relevant practitioners or health care organizations at least annually after implantation of the ventricular assist device to ascertain any additional needs the patient may have related to implantation of the ventricular assist device.*

CT.3 The program shares information about the participant's disease or condition across the entire continuum of care to any relevant setting or practitioner.	1	The program shares information directly with the participant and/or family.
	2	The program shares information with other relevant practitioners or health care organizations as needed.
CT.4 Information management processes meet the program's internal and external information needs.	1	Data are easily retrieved in a timely manner without compromising security and confidentiality.
	2	The program has determined how long health records and other data and information are retained in accordance with applicable law and patient need.
	3	The program defines, captures, analyzes, transmits, and reports aggregate data and information that supports managerial decisions, operations, PI activities, and participant care.
CT.5 The program initiates, maintains, and makes accessible a health or medical record for every participant.	1	Practitioners have access to all needed participant information as necessary.
	2	The record contains sufficient information to identify the patient or the participant (if other than the patient); support the diagnosis; justify care, treatment, and services; and document the course and results of care, treatment, and services.

	3	The record contains sufficient information to track the patient's movement through the care system and facilitate continuity of care both internally and externally to the program.
	4	Records are periodically reviewed for completeness, accuracy, and timely completion of all necessary information.

[1] Programs are highly encouraged to enter patients who have a ventricular assist device as a bridge to transplant into national, audited registries. This will allow the program to easily track information for quality improvement purposes.

[2] Acceptable ventricular assist device procedures include placement of long-term devices or placement of long-term devices as part of studies for FDA approval.

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